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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

OREXO AB, : Honorable Freda L. Wolfson, U.S.D.J. Plaintiff, : Honorable Lois H. Goodman, U.S.M.J.

v. : Civil Action No. 3:11-cv-03788 (FLW)(LHG)

MYLAN PHARMACEUTICALS INC. and MYLAN INC.,

Defendants.

OREXO AB'S MEMORANDUM IN OPPOSITION TO MYLAN PHARMACEUTICALS INC. AND MYLAN INC.'S MOTION TO SEAL PORTIONS OF THE JULY 6, 2012 LETTER AND EXHIBITS TO THE JULY 8, 2012 LETTER

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Plaintiff Orexo AB opposes Defendants Mylan's motion to seal non-confidential information in Mylan's July 6, 2012 letter to the Court and in exhibits to Orexo's July 8, 2012 response (the "July 16 Motion to Seal"). Mylan previously sought to seal this *same non-confidential information* in its July 13, 2012 Motion to Seal (the "July 13 Motion to Seal"), which has already been fully briefed by the parties (*see* Dkt. Nos. 66, 71, 74 and 75). Orexo opposes Mylan's current Motion to Seal for the substantially same reasons set forth in its July 23, 2012 Opposition (Dkt. No. 71) and July 31, 2012 Sur-reply (Dkt. No. 75), which are incorporated herein by reference. Accordingly, Mylan's July 13 Motion to Seal and July 16 Motion to Seal should stand or fall together.

I. FACTS

Mylan's motion seeks to designate its claim constructions and supporting evidence as confidential. Contrary to Mylan's argument, this information is not confidential. Rather, it concerns: (1) Mylan's proposed claim constructions which should be based on publicly available information and would be part of the public record when the Court enters a claim construction ruling; (2) the publicly available patent-in-suit and publicly available file history; and (3) descriptions of expert testimony on the teachings of the publicly available patent and prior art. This information does not include even one citation to Mylan confidential information such as Mylan's ANDA.

Mylan did not designate this information as confidential when it exchanged its

Preliminary or Responsive Claim Construction Charts pursuant to N.J. L. Pat. R. 4.2(a)-(c), when
the parties conferred pursuant to N.J. L. Pat. R. 4.2(d); or when the parties exchanged Draft Joint

Claim Construction Statements. Counsel for Orexo has relied on Mylan's previous disclosures as non-confidential and disclosed Mylan's proposed constructions and support to Orexo.

II. LEGAL STANDARD

Mylan, as the party seeking to seal portions of its July 6, 2012 letter to the Court and the exhibits to Orexo's July 8, 2012 response must show (1) "that the material is the kind of information that courts will protect"; and (2) "disclosure will work a clearly defined and serious injury to the party seeking closure." *See In re Cendant Corp.*, 260 F.3d 183, 192 (3d Cir. 2001) (holding that the district court abused its discretion by issuing confidentiality order sealing documents) (internal citations and quotations omitted).

A party may properly shield its confidential or proprietary information from public view under certain, limited circumstances. *See* Fed. R. Civ. P. 26(c). Mylan must show (a) the nature of the materials are of the type that should be protected, (b) the legitimate private or public interests which warrant the relief sought, (c) the clearly defined and serious injury that would result if the relief sought is not granted, and (d) why a less restrictive alternative to the relief sought is not available. N.J. Loc. Civ. R. 5.3(c)(2); *see also* Orexo v. Mylan Discovery Confidentiality Order of March 26, 2012, at ¶ 12 (confirming burden in motion to seal remains on party claiming confidentiality).

¹ In its Draft Joint Claim Construction Statement, Mylan indicated that two direct references to Mylan's ANDA product were confidential, but failed to identify any other portion as confidential. These two references were subsequently removed before the Joint Statement was submitted to the Court and are not at issue in this motion.

III. ARGUMENT

Prior to this motion and despite being the subject of the parties' exchanges under L. Pat. R. 4.2 and 4.3, Mylan did not designate its (or Orexo's) proposed constructions or its (or Orexo's) evidentiary support as "Confidential." Counsel for Orexo has relied on this previous decision not to designate and disclosed Mylan's claim construction positions to Orexo while discussing its own positions. Mylan should not be permitted to seal its proposed constructions and large portions of the support without meeting its burdens under the rules to specifically identify the confidential information and Mylan's need to seal.

A. MYLAN HAS NOT SPECIFICALLY IDENTIFIED HOW THE INFORMATION IT SEEKS TO SEAL RELATES TO MYLAN CONFIDENTIAL INFORMATION.

Mylan does not meet its burden of demonstrating need. Nowhere does Mylan indicate how the information that relates only to construction of Orexo's patent and claims could possibly reveal Mylan's confidential information. Mylan only broadly alleges that Mylan's and Orexo's claim constructions and supporting evidence include information from the ANDA. But, Mylan's constructions and supporting evidence do not cite its ANDA or describe its ANDA formulation in any manner. Mylan fails to connect the dots, by failing to identify the nature of the confidential material included in the letter and exhibits, see N.J. L. Civ. R. 5.3(c)(2)(a). Mylan's support is insufficient to justify restricting public access to the proposed claim constructions; citations to the '910 Patent's claims, specification, and file history in support of those claim constructions; and publicly-available extrinsic evidence.

Orexo does not agree that Mylan's proposed constructions or citations to publicly available evidence should be considered confidential. If there are specific portions of Mylan's proposed constructions and supporting evidence that Mylan believes contains confidential

information, it should identify these sections to this Court and to Orexo with an explanation concerning exactly how this information reveals Mylan's confidential information so that the Parties can further consider this matter.

B. MYLAN'S PROPOSED CONSTRUCTIONS OF THE OREXO PATENT CLAIMS SHOULD NOT CONTAIN MYLAN CONFIDENTIAL INFORMATION.

In seeking to seal its proposed claim constructions, Mylan asks this Court to remove from public view these proposed constructions, which by definition address the meaning of the claims of the publicly available patent-in-suit. It is Orexo's (not Mylan's) patent and claims that are the subject of these construction proceedings. Thus, these proposed constructions cannot reasonably be considered confidential. If Mylan's logic is accepted, this Court would be required to seal its rulings on the meaning of claim language in Orexo's publicly available '910 patent – an odd result to say the least.

Nor should Mylan's supporting evidence contain Mylan's confidential information. This evidence includes citations to, characterizations of, and proposed expert testimony regarding the patent specification, the prosecution history and prior art – all of which are publicly available. If Mylan believes that the public record supports its claim constructions, then its proposed claim constructions must likewise be non-confidential.

Mylan seeks to redact references to a specific material (not identified here to avoid the need for further motions to seal) in its July 6, 2012 letter. In its July 30, 2012 Reply Brief in support of the July 13 Motion to Seal, Mylan admitted that the only reason it seeks to address this unnamed material in its construction is because it is present in Mylan's ANDA product. That is plainly improper and highlights the weakness of the argument (as Orexo will address in claim construction briefing). But, Mylan previously and incongruously argued in its Joint Claim Construction Statement that the '910 patent specification and file history supported a claim

construction excluding this unnamed material. Given this position (that even Mylan now admits is wrong), Mylan cannot reasonably argue that the reference to the unnamed material should be sealed. By expressly naming the "unnamed material" in its construction, Mylan destroys any justification for sealing references to that unnamed material.

C. MYLAN HAS IMPROPERLY IDENTIFIED ITS ANDA INFORMATION AS "HIGHLY CONFIDENTIAL"

Mylan alleges that the exhibits to Orexo's July 8, 2012 letter contain information relating to Mylan's ANDA product, yet Mylan has incorrectly designated these as "Highly Confidential" (and not "Confidential") under the Protective Order. The protective order entered in this case provides:

"The designation 'Confidential' shall be limited to information that the Producing Party, Including a third party, in good faith believes to contain: (1) proprietary or commercial sensitive information concerning the formulation or composition of products ... For the avoidance of doubt, the following information shall be of the type considered 'Confidential' and not 'Highly Confidential' under this order: (1) All portions of ANDA 20-2657 ... (4) all documents relating to the composition, manufacture, specification, testing, analysis, makeup, content, ingredients, development and structure of Mylan's ANDA products."

While Orexo disagrees that July 6 letter and exhibits to the July 8 letter contain ANDA information, to the extent Mylan believes certain disclosures reveal information about Mylan's ANDA product and the court permits sealing, this information should be designated (or redesignated) pursuant to the court's Protective Order as "Confidential" and not "Highly Confidential."

IV. **CONCLUSION**

For the reasons set forth above, Mylan's Motion to Seal should be denied.

Respectfully submitted

s/John E. Flaherty Dated: August 6, 2012 By:

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of OREXO AB'S MEMORANDUM IN OPPOSITION TO MYLAN PHARMACEUTICALS INC. AND MYLAN INC.'S MOTION TO SEAL PORTIONS OF THE JULY 6, 2012 LETTER AND EXHIBITS TO THE JULY 8, 2012 LETTER were caused to be served on August 6, 2012, upon the following via e-mail and/or the CM-ECF system:

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